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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/446, 996 12/30/99 VAN GROENINGHEN J 49477 (1958)

HM12/0629

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EXAMINER

ANDRES, J

ART UNIT	PAPER NUMBER
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1646

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/446,996	VAN GROENINGHEN, JOHANNES CHRISTIANUS
Examiner	Art Unit	
Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2001 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 1-9 and 12 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 10,11 and 13 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 30 December 1999 is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 20) Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group II, claims 10, 11, and 13, and species election of GnRH agonists in Paper No. 7 is acknowledged. Claims 1-9 and 12 are withdrawn from consideration as being drawn to a non-elected invention. The restriction requirement is made FINAL.

Priority

2. Applicant's priority claim based on PCT/DE/98/01902, 3 July 1998, and German application 197 28 737 .9, 4 July 1997, is acknowledged. The ribbon copy of the German application has been received.

Drawings

3. The drawings are objected to because they contain figure headings. Correction is required.

Specification

4. The disclosure is objected to because of the following informalities: "Mamma" appears repeatedly when "mammary" is obviously intended. "Arachnoidonic" appears on p. 2, line 21, when "arachidonic" is presumably intended.

The "Brief Description of Drawings" is missing.

The title is objected to because of its length. The title should be both concise and descriptive.

Appropriate correction is required.

The use of trademarks has been noted throughout this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 10, 11, and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A “use” is not patentable; the claims should be drawn to methods. For examination purposes, the claims will be interpreted as being drawn to methods.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte*

Forman, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

What is claimed is a method of treatment of cancer. While relevant clinical studies are outlined, they are proposed studies and have not been carried out. All that has been described is the presence of GnRH receptors on some tumor samples. No objective evidence is set forth to allow one of skill in the art to predict that these receptors could be found *in vivo* in the types of cancer broadly claimed. Further, it is not predictable, absent guidance to that effect, that all tumors possessing the GnRH receptor could successfully be treated as claimed. The receptor levels vary dramatically (table II, p. 24) and there is no indication as to what level of receptor is necessary to be predictive of the desired response. Inhibition of cell growth is shown only for a malignant melanoma cell line; there is no guidance presented to correlate the inhibition with the receptor levels or to indicate that the amount of inhibition reported in the specification would be predictive of *in vivo* success. Further, while treatment with GnRH analogs is known in the art for hormone-responsive tumors, it is not predictable that these methods could be extrapolated to any and all tumors bearing the GnRH receptors. Compagni et al. (British J. Cancer 2000, vol. 83, pages 1-5), for example, teaches that many lesions can result in tumorigenesis; not all tumors are hormone responsive and one of skill in the art would not be able to predict, based on the instant disclosure, which would be. Cancer is a complex disease and tumor cells can escape from apoptotic stimuli by a variety of means.

Additionally, the claims encompass all GnRH agonists, including those not yet known in the art. The efficacy of any particular compound is dependent on many variables, including pharmacological and physiological, as well as biochemical factors. Because of the complex

nature of all of these factors, it is not predictable which agonists would function as claimed. To test the many possibilities without such predictability of success would be well outside the realm of routine experimentation.

For these reasons there is insufficient guidance allow a predictability of success and thus it would require undue experimentation for one of skill in the art to use the invention as claimed.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10, 11, and 13 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to uses of GnRH agonists. However, "agonist" is not defined in the specification so that one of skill in the art would know what activities, and what level of a given activity, could be considered to be agonistic.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
June 28, 2001

Yvonne Eyler
YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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